

Proposed Addition to Division of Medical Assistance N.C. Prior Authorization Program Growth Hormones
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Therapeutic Class Code: P1A, P7A

Therapeutic Class Description: Growth Hormones

Medication	Generic Code Number(s)	National Drug Code(s)
Genotropin (Human Growth Hormone)	63351, 10554, 63408	
Genotropin Miniquick products:	21450, 21451, 21452, 21453, 21454, 50207, 50217, 50177, 50187, 50197	
Humatrope (Human Growth Hormone)	00575, 25957, 25963, 25969	
Norditropin (Human Growth Hormone); Norditropin 15mg/1.5ml, Norditropin Nordiflex:	24145, 24146, 24147, 63407, 92376, 92386	00169777411
Nutropin, Nutropin Depot (Human Growth Hormone)	25967, 25954, 91404, 91405, 91406, 17475	50242001902, 50242001966, 50242003249, 50242007201, 50242007202, 50242007203
Omnitrope (Human Growth Hormone)	93215	
Saizen (Human Growth Hormone)	12767, 23695	44087100502, 54569493000
Tev-Tropin (Human Growth Hormone)		57844071319, 57844071341
Zorbtive	12767	
Increlex	25465	
Accretropin		

Use of Serostim for AIDS wasting syndrome is exempted from this policy and does not require prior approval.

Early and Periodic Screening, Diagnosis and Treatment Provision

Early and Periodic Screening, Diagnosis and Treatment (EPSDT) allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are medically necessary health care services to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service product or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

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EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at <http://www.ncdhhs.gov/dma/EPSDTprovider.htm>.

Criteria (excludes Zorbtive and Increlex)

A. Adults with growth hormone deficiency:

Coverage is provided in the presence of all the following:

- 1) Biochemical diagnosis of somatotropin deficiency by means of a negative response to a standard growth hormone stimulation test
- 2) This deficiency either alone or with multiple hormone deficiencies is a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma.

B. Children with growth hormone deficiency:

Coverage is provided in the presence of all the following:

- 1) Growth hormone dysfunction or lack of adequate endogenous growth hormone documented by any of two provocative tests of less than 10mg/ml
- 2) Patient's height must be below the third percentile for their age and gender related height.
- 3) Epiphysis confirmed as open in patients greater than 9 years of age.

A growth response of greater than 4.5 cm/year (pre-pubertal growth phase) or greater than 2.5 cm/year (post-pubertal growth phase) must occur for continuation of coverage.

C. Coverage is provided in the absence of documented growth hormone deficiency in the following situations:

- 1) Patients with Turner's syndrome
- 2) Children with height less than 3rd percentile for chronologic age with chronic renal insufficiency.
- 3) Patients with Praeder-Willi syndrome
- 4) ~~Patients with Short Bowel Syndrome (Zorbtive only)~~
- 5) ~~4~~ Children who were born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) in whom the birth weight and/or length were more than 2 standard deviations below the mean for gestational age, and who fail to show catch-up growth by age 2 (defined as a height velocity below 1 standard deviation score, adjusted for age).

Increlex

Therapy with Increlex (IGF-I) must be reserved for children with growth failure that will not respond to GH therapy: those with GH resistance caused by a mutation in the GH receptor or post-GH receptor signaling pathway, IGF-I gene defects, and individuals with GH gene deletions who have developed neutralizing antibodies to GH. In addition, children with severe short stature may be considered for Increlex therapy if they have

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failed a trial of GH therapy. Children must have a height less than 3 SDs below the mean, an IGF-I level less than 3 SDs below the mean, and normal or elevated GH levels.

Zorbtive

Therapy with Zorbtive must be reserved for patients with short bowel syndrome.

Procedures

1. The P&T recommends that a pharmacist handle all prior authorization requests for this therapeutic class.
2. The request must come from the physician's office.
3. Approval length up to one year.

References

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6. Rapaport R, Tuvemo T. Growth and growth hormone in children born small for gestational age. Acta Paediatrica Paediatrica. 2005. 94:1348-1355.
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